

**REMARKS**

**I. INTRODUCTION**

Claims 1-33 were previously cancelled. The Specification has been amended. No new matter has been added. Claims 34 - 60 are pending in the present application. In view of the above amendments and the following remarks, it is respectfully submitted that these claims are in condition for allowance.

**II. THE OBJECTION TO THE SPECIFICATION SHOULD BE WITHDRAWN**

The Examiner has objected to the specification for failing to provide proper antecedent basis for the claimed subject matter of claims 36-43, 46-48, 51, and 57-60. (See 3/2/10 Office Action, p. 2).

Regarding claims 36-43, these claims relate to further embodiments of the angle for the projected hole axes. The Specification states that "at least two of said (projected) hole axes 6 are at an angle  $\alpha$  greater than zero and less than  $90^\circ$  with respect to each other." (See Specification, p. 7, ll. 22-24). Therefore, the Specification also discloses any angle that falls within the range of zero and ninety degrees. Each of the claims 36-43 includes a recitation that falls within this acceptable range. However, to expedite processing of the present application, the Specification has been amended to include the exemplary angles of  $\alpha$ . Thus, it is respectfully submitted that the Examiner should withdraw the objection to claims 36-43.

Regarding claims 46-48, these claims relate to a distance measured from the tip of a nail body to the axis of the transverse hole furthest from the tip. The independent claim to which claims 46-48 depend therefrom recites that the distance  $x$  is less than  $2(n)(d)$ . The Specification discloses this measurement. (See Specification, p. 4, ll. 11-13). Therefore, any distance that is

less than  $2(n)(d)$  is an acceptable measurement. Claim 46 recites that the distance  $x$  is less than  $1.8(n)(d)$ , an acceptable measurement. Claim 48 recites that the distance  $x$  is less than  $1.4(n)(d)$ , another acceptable measurement. Claim 47 recites that the distance  $x$  is less than  $1.5(n)(d)$ , which is both an acceptable measurement and even specifically disclosed in the Specification. (See Specification, p. 4, ll. 13-14). However, to expedite processing of the present application, the Specification has been amended to include the exemplary measurements of  $x$  recited in claims 46 and 48. Thus, it is respectfully submitted that the Examiner should withdraw the objection to claims 46-48.

Regarding claim 51, the Specification includes a disclosure reciting language that fully supports the recitation of claim 51. Specifically, the Specification states that “the two intersecting through holes may be located at the same distance  $d$  from said tip of the nail and preferably are spaced  $88-92^\circ$  apart.” (See Specification, p. 4, ll. 21-23). Thus, it is respectfully submitted that the Examiner should withdraw the objection to claim 51.

Regarding claims 57-60, the Specification includes a respective disclosure reciting language that fully supports the recitations of each of claims 57-60. In fact, the Specification uses common variables as those used in each claim. Regarding claim 57, the Specification states that “[t]he distance  $(a)$  between the tip of the nail and that through hole which nearest to the tip (7) may be  $(a) \leq 5d$ , and preferably  $(a) \leq 1.5(d)$ , whereby  $d$  is the diameter of the through hole.” (See Specification, p. 5, ll. 14-17). Regarding claim 58, the Specification states “[i]n a preferred embodiment a plurality of  $n$  through holes are provided in the nail whose centres are located at a distance  $x$  from said tip which is comprised in the range of  $1.05(n)(d) \leq x \leq 3.00(n)(d)$ .” (See Specification, p. 5, ll. 19-23). Regarding claim 59, the Specification states “[i]n a further preferred embodiment a plurality of  $n$  through holes are provided in the nail whose centres are located at a distance  $x$  from the tip which is smaller than  $4d + (n-1)(2.2d)$ .” (See Specification, p. 5, ll. 25-27). Regarding claim 60, the Specification states “[p]referably the distance ‘ $b$ ’ between the axes of the two adjacent through holes is  $b \leq 1.5d$ .” (See Specification, p. 6, ll. 1-2).

Therefore, it is clear that the recitations of claims 57-60 are fully supported by the Specification which provides the proper antecedent basis. Thus, it is respectfully submitted that the Examiner should withdraw the objection to claims 57-60.

### **III. THE 35 U.S.C. §112 REJECTION SHOULD BE WITHDRAWN**

Claim 53 stands rejected under 35 U.S.C. §112, first paragraph, for failing to comply with the written description requirement. (See 3/2/10 Office Action, p. 2). Specifically, the Examiner states that the phrase “at least a portion with a conical shape” seeks to introduce new matter. However, the Specification states “[f]urthermore a portion of one or more screw holes may be substantially conical in geometry.” (See Specification, p. 5, ll. 6-7). Thus, it is respectfully submitted that claim 53 complies with the written description requirement and the Examiner should withdraw the 35 U.S.C. §112, first paragraph, rejection for this claim.

Claim 50 stands rejected under 35 U.S.C. §112, second paragraph, for being indefinite. (See 3/2/10 Office Action, p. 2). Specifically, the Examiner states that the phrase “wherein at least two of the transverse holes at least partially intersect one another” renders the claim vague and indefinite since it is unclear what structure is being claimed. The Examiner further states that it appears that this recitation is meant to state that the hole axes intersect one another. Initially, independent claim 45 to which claim 50 depends recites “at least three transverse holes extending through the distal end of the nail body” which may be considered a bore hole for purposes of the present argument. As supported in the Specification, Figs. 3-5 provide drawings for intersecting through holes with a corresponding disclosure in the Specification. Because the transverse holes are bores with a circular area that extends, for example, in a cylindrical path, a partial intersection may occur between two transverse holes. Furthermore, it is respectfully submitted that the Examiner is misplaced in assuming claim 50 to mean that the hole axes intersect one another. Although Figs. 3-5 relate to an embodiment in which the hole axes intersect, again, because of the three-dimensional aspect of the transverse holes, it is possible for

a partial intersection in which the axes of the holes never intersect. For example, the hole axes may be skew. Thus, it is respectfully submitted that claim 50 is definite and clear on its face. Therefore, it is respectfully submitted that the Examiner should withdraw the 35 U.S.C. §112, second paragraph, rejection for claim 50.

#### **IV. THE 35 U.S.C. §103(a) REJECTIONS SHOULD BE WITHDRAWN**

Claims 34 - 48, 50, 51, and 53 - 60 stand rejected under 35 U.S.C. 103(a) as unpatentable over U.S. Patent No. 6,120,504 to Brumback et al. (hereinafter "Brumback) in view of U.S. Patent No. 5,472,444 to Huebner et al. (hereinafter "Huebner"). (See 3/2/10 Office Action, p. 3).

Claim 34 recites an intramedullary nail comprising "a nail body having a longitudinal axis, a proximal end configured and dimensioned for coupling to an insertion device, and a distal end having a tip configured and dimensioned for insertion into the intramedullary canal of a long bone" in combination with "at least three transverse holes extending through the distal end of the nail body, each transverse hole defining a hole axis, and all three transverse holes grouped at the distal end within a distance  $x$  measured from the tip of the nail body to the axis of the transverse hole furthest from the tip, wherein a projection of the three hole axes of the at least three transverse holes in a plane orthogonal to the longitudinal axis is such that at least two of the projected hole axes are at an angle  $\alpha$  with respect to one another, where  $0 < \alpha < 90^\circ$ , and *where the distance  $x \leq 25d$ , where  $d$  is either the diameter of the largest of the at least three transverse holes or  $d$  is the mean diameter of the at least three holes.*"

The Examiner implies that Brumback does not disclose or suggest the distance of the holes from the tip of the intramedullary nail being less than or equal to twenty five times the diameter of the largest transverse hole or the mean diameter of the transverse holes. The Examiner attempts to cure this deficiency with Huebner by stating that Huebner discloses that the distal tip portion extends about 20-50% the length of the nail beyond the distal most hole to

reduce stress concentrations. (See 3/2/10 Office Action, citing Huebner, col. 3, ll. 15-18; col. 4, ll. 30-33). The Examiner further correctly states that neither Brumback nor Huebner relate the distance from the hole axis of the proximal most transverse hole to the distal tip of the nail. However, the Examiner states that the recited distance of claim 34 is obvious since discovering an optimum or workable range involves only routine skill in the art.

It is respectfully submitted that Brumback or Huebner indeed do not disclose or suggest that “the distance  $x \leq 25d$ , where  $d$  is either the diameter of the largest of the at least three transverse holes or  $d$  is the mean diameter of the at least three holes,” as recited in claim 34. However, the Examiner’s contention that the recited distance  $x$  in claim 34 being obvious to have been optimized and merely being one discoverable by routine skill in the art is misplaced. As stated in the Specification, “[a] disadvantage of the known nails is the fact that the distal holes are *unnecessarily* far from the distal nail tip which produces a nail-weakening effect.” (See Specification, p. 1, ll. 17-20). Claim 34 is directed toward at least addressing this particular disadvantage. The Examiner’s premise is therefore misplaced as the nail in Huebner is a nail exhibiting the condition where the holes are far from the distal nail tip. That is, the nail in Huebner includes holes and also a distal tip portion that extends beyond the distal-most hole about 20-50% of the nail length (*i.e.*, “distal holes” being far from the distal tip).

The Specification further includes other disadvantages of known nails such as parallel holes being spaced too close to one another, widely spaced parallel or orthogonal holes, and an unnecessarily loose fit to the hole in the nail by the screws traversing the nail. (See Specification, p. 1, l. 22 - p. 2, l. 15). It is respectfully submitted that both Brumback and Huebner teaching known nails and configured as taught therein fit at least one of the disadvantages that the nail of claim 34 is seeking to address. For example, the nail of Brumback potentially includes an unnecessarily loose fit for a traversing screw such as distal slot 24 and/or proximal slot 25. Because the nails of Brumback and Huebner include at least one of the disadvantages that claim 34 is seeking to address, it is respectfully submitted that the distance  $x$

recited in claim 34 is not merely a discoverable range that one of ordinary skill in the art would reach through routine skill. It is further respectfully submitted that the novel clustering of the transverse holes in the distal end of the nail within the recited range provides the remedy to the above known disadvantages of known nails. Therefore, the distance  $x$  and the relationship of the distance  $x$  to the diameter  $d$  is neither obvious nor discoverable through routine skill in the art.

Thus, it is respectfully submitted that neither Brumback nor Huebner, either alone or in combination, discloses or suggests “all three transverse holes grouped at the distal end within a distance  $x$  measured from the tip of the nail body to the axis of the transverse hole furthest from the tip,” “where the distance  $x \leq 25d$ , where  $d$  is either the diameter of the largest of the at least three transverse holes or  $d$  is the mean diameter of the at least three holes,” as recited in claim 34. Accordingly, it is respectfully submitted that claim 34 is allowable and the Examiner should withdraw the 35 U.S.C. §103(a) rejection for this claim. Because claims 35-44 depend from and, therefore, include the limitations of claim 34, it is respectfully submitted that these claims are also allowable.

Claim 45 includes a recitation substantially similar to claim 34 including “the distance  $x < 2(n)(d)$ , where  $n$  is the number of transverse holes grouped within the distance  $x$  from the tip of the nail body and  $d$  is either the diameter of the largest of the at least three transverse holes or  $d$  is the mean diameter of the at least three holes.” Thus, it is respectfully submitted that claim 45 is allowable for at least the reasons discussed above with reference to claim 34. Because claims 46-48, 50-51, and 53-55 depend from and, therefore, include the limitations of claim 45, it is respectfully submitted that these claims are also allowable.

Claim 56 also includes a recitation substantially similar to claim 34 including “a distance  $a$  between the tip and the transverse hole closest to the tip is  $a \leq 5d$ .” Thus, it is respectfully submitted that claim 56 is allowable for at least the reasons discussed above with reference to claim 34. Because claims 57-60 depend from and, therefore, include the limitations of claim 56,

it is respectfully submitted that these claims are also allowable.

Claim 49 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Brumback in view of Huebner in further view of U.S. Patent No. 5,041,115 to Frigg et al. (hereinafter "Frigg"). (See 3/2/10 Office Action, p. 4). Claim 52 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Brumback in view of Huebner in further view of U.S. Patent No. 5,766,174 to Perry. (See 3/2/10 Office Action, p. 5). Brumback and Huebner were discussed above. Claim 45 was recited above.

As discussed above, neither Brumback nor Huebner, either alone or in combination, discloses or suggests "the distance  $x < 2(n)(d)$ , where  $n$  is the number of transverse holes grouped within the distance  $x$  from the tip of the nail body and  $d$  is either the diameter of the largest of the at least three transverse holes or  $d$  is the mean diameter of the at least three holes," as recited in claim 45. It is respectfully submitted that neither Frigg nor Perry discloses or suggests this recitation of claim 45. Thus, it is respectfully submitted that neither Brumback, Huebner, Frigg, nor Perry, either alone or in combination, discloses or suggests this recitation of claim 45. Because claims 49 and 52 depend from and, therefore, include the limitations of allowable claim 45, it is respectfully submitted that these claims are also allowable.

**CONCLUSION**

In light of the foregoing, Applicant respectfully submits that all of the pending claims are in condition for allowance. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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